UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

MARIA LUISA GARZA, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. 2:12-CV-198
	§	
WYETH LLC; fka WYETH; dba WYETH, INC., *et al*,	§	
	§	
	§	
Defendants.	§	

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Before the Court is Defendants TEVA Pharmaceuticals USA, Inc., Pliva, Inc., Barr Laboratories, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc.'s Motion to Dismiss (D.E. 57.) Defendant Barr Pharmaceutical, LLC joins in the motion as well. (D.E. 65.) These Defendants are collectively referred to herein as the "Generic Defendants." For the reasons set forth below, the motion to dismiss is GRANTED IN PART AND DENIED IN PART.

PROCEDURAL AND FACTUAL BACKGROUND

The Court heard oral arguments on the motion to dismiss on December 21, 2012. (Transcript available at D.E. 69.) Following the hearing, the Court granted Plaintiffs leave to amend their complaint. (D.E. 68.) The Court's analysis is therefore based on the factual allegations set forth in Plaintiffs' Fourth Amended Complaint. (D.E. 72.) The relevant facts from the complaint, which for purposes of this motion must be accepted as true and viewed in the light most favorable to Plaintiffs, are as follows.

This action is brought by Plaintiff Maria Luisa Garza and her husband, Plaintiff Oscar Garza, Sr. Ms. Garza seeks to recover compensatory damages for mental anguish, physical

disfigurement, physical impairment, loss of earnings, and reasonable and necessary medical expenses, in addition to exemplary damages. Mr. Garza seeks to recover compensatory damages for loss of consortium and loss of household services, as well as exemplary damages.

Ms. Garza alleges her injuries resulted from being prescribed and ingesting the prescription drug Reglan/metoclopramide HCl (hereinafter "metoclopramide") over an extended period of time. Ms. Garza's physician first prescribed metoclopramide at a dosage of 10mg in June 2007 to treat gastroesophageal reflux disease. In July 2009, Ms. Garza began exhibiting abnormal muscle movements, which have since been linked to her overexposure to the drug. Prolonged exposure to metoclopramide is known to cause injuries to the central nervous system and the extrapyramidal motor system. Some patients develop tardive dyskinesia, a severe and often permanent neurological movement disorder.

Labeling approved by the United States Food and Drug Administration (FDA) for metoclopramide last appeared in the Physician's Desk Reference in 2002. In 2003, the FDA approved the addition of new warnings to be added to the drug's label. In July 2004, the FDA approved the addition of a bolded warning to the label for metoclopramide stating that therapy with the drug "should not exceed 12 weeks in duration." And in February 2009, the FDA ordered a black box warning, its strongest, stating that "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases."

During the time that Ms. Garza was prescribed and ingested metoclopramide, Generic Defendants were engaged in the business of testing, manufacturing, labeling, marketing, distributing, promoting, and/or selling either directly or indirectly, through third parties or related entities, metoclopramide in the State of Texas and in interstate commerce. Generic Defendants

TEVA Pharmaceuticals USA, Inc. (TEVA), Watson Laboratories, Inc. (Watson Labs), and Watson Pharma, Inc. (Watson Pharma) failed to update their labels to match the 2003, 2004, and 2009 label changes required by the FDA. Generic Defendants TEVA, Watson Labs, and Watson Pharma additionally failed to timely inform Ms. Garza or her healthcare providers via letter or other communication about the new, FDA-approved changes to the labels. As a result, Ms. Garza and her physicians were unaware of the risks and warnings about metoclopramide therapy exceeding twelve weeks. Had Ms. Garza and her physicians understood the nature and extent of the risk posed, her physicians would not have prescribed the medication past twelve weeks, and Ms. Garza would not have taken the drug past twelve weeks.

LEGAL STANDARD

On a Rule 12(b)(6) or 12(c) motion to dismiss, the Court must examine the complaint in the light most favorable to Plaintiffs, accepting all allegations as true and drawing all reasonable inferences in favor of Plaintiffs. *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982); *Piotrowski v. City of Houston*, 51 F.3d 512, 514 (5th Cir. 1995). The Court need not, however, accept as true legal conclusions masquerading as factual allegations, and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plaintiffs must allege sufficient facts that give rise to a reasonable inference that Defendants are liable. *Id.*; *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). The factual allegations must raise Plaintiffs' claim for relief above the level of mere speculation. *Twombly*, 550 U.S. at 555. As long as the complaint, taken as a whole, gives rise to a plausible inference of actionable conduct, Plaintiffs' claims should not be dismissed. *Id.* at 555–56. This test of

pleadings is devised to balance Plaintiffs' right to redress against the interests of the parties and the Court in minimizing expenditures of time, money, and resources. *Id*. at 557–58.

ANALYSIS

In their motion to dismiss, Generic Defendants seek dismissal of all claims against them in this suit. Generic Defendants argue that Plaintiffs' claims must be dismissed because they are (A) preempted by federal law under the United States Supreme Court's recent decision in *Pliva, Inc. v. Mensing*, --- U.S. ----, 131 S. Ct. 2567 (2011), and (B) otherwise barred by a rebuttable presumption of no liability arising under TEX. CIV. PRAC. & REM. CODE § 82.007.

A. *Mensing*

Generic Defendants argue that Plaintiffs' failure-to-warn claims[1] are indistinguishable from those that the Supreme Court concluded were preempted by federal law in *Mensing*. (D.E. 57 at 5–10.) In the case at hand, however, Plaintiffs' claims against Generic Defendants TEVA, Watson Labs, and Watson Pharma can be distinguished on the facts from those asserted by the plaintiffs in *Mensing*. In *Mensing*, the generic drug manufacturers' labels matched the brand-name manufacturers' FDA-approved labels. In the case at hand, Generic Defendants TEVA, Watson Labs, and Watson Pharma failed to update their labels to conform with important changes made to the brand-name label by the FDA in 2003, 2004, and 2009. Here, Plaintiffs allege that Generic Defendants TEVA, Watson Labs, and Watson Pharma failed to comply with

[1] Numerous Texas courts have concluded that the only valid claim in a prescription drug suit for personal injuries is that the drug manufacturer failed to adequately warn the plaintiff's prescribing physician about the potential dangers of the drug. *See, e.g.*, *Del Valle v. Pliva, Inc.*, Civ. A. No. B:11-113, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011); *In re Norplant*, 955 F. Supp. 700, 710 (E.D. Tex. 1997), *aff'd* 165 F.3d 374 (5th Cir. 1999). This is so due to the learned intermediary doctrine, which limits a drug manufacturer's liability provided the manufacturer provided adequate warnings to the plaintiff's physician. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012). Plaintiffs do not dispute the application of this well-established doctrine to the case at hand. Accordingly, the Court concludes that, for purposes of the present motion to dismiss, the only valid claim before the Court is that Generic Defendants failed to adequately warn Ms. Garza's physicians of the dangers associated with the long-term use of metoclopramide.

a duty under state law that was coextensive with their duties under federal law; whereas, in *Mensing*, the state law duty conflicted with federal requirements.

Under Texas law, a manufacturer must warn consumers about dangers associated with its product of which it has actual or constructive knowledge at the time the product is sold. *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984); *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986); *Harper v. E.I. DuPont de Nemours & Co.*, No. 01-94-01191, 1997 WL 69858, at *12 (Tex. App.—Houston [1st Dist.] Feb. 20, 1997). For drug manufacturers, it is sufficient that they warn the prescribing physician of the dangers associated with the use of their products. *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012); *Harper*, 1997 WL 69858, at *12. Accordingly, where a drug's label is inadequate or misleading, under Texas law, a drug manufacturer may be held liable for injuries sustained by the consumer resulting from a failure to properly warn about the dangers of the drug.

Under federal law, a generic drug manufacturer may obtain approval of a drug from the FDA simply by showing equivalence to a reference-listed drug that has already undergone clinical trials and gained approval from the FDA. 21 U.S.C. § 355(j)(2)(A). A generic drug manufacturer has the responsibility to ensure that the labeling for the generic drug is the same as the labeling approved for the listed drug. 21 U.S.C. §§ 355(j)(2)(A)(v) & (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8) & 317.127(a)(7). The FDA interprets these regulations as imposing an ongoing duty for generic manufacturers to update their product labels to ensure the sameness of the generic and name-brand drug labels. *Mensing*, 131 S. Ct. at 2575; 57 Fed. Reg. 17961 (1992) ("ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval").

Under federal law, a generic drug manufacturer may update or strengthen a warning or precaution on its label without preapproval from the FDA to match an updated brand-name label or to comply with instructions from the FDA. *Mensing*, 131 S. Ct. at 2575; 21 C.F.R. §§ 314.70(c)(6)(iii)(A) and 314.94(a)(8)(iv). A generic manufacturer cannot, however, unilaterally strengthen its warning label, which is what the plaintiffs in *Mensing* argued was required of the defendant manufacturers under state law. *Id*. Because the state law required the generic drug manufacturers to do something that was prohibited under federal law, the Supreme Court concluded that the state law was preempted. *Mensing*, 131 S. Ct. at 2580 ("When the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established preemption."). The Supremacy Clause of the United States Constitution requires that state law give way where it conflicts with federal law; for instance, where it is "impossible for a private party to comply with both state and federal requirements." *Mensing*, 131 S. Ct. at 2577; *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

In the case at hand, there is no such conflict. Generic Defendants' duty under Texas law to adequately warn consumers about the potential dangers of their drugs is coextensive with their duty under federal law to ensure that their labeling is the same as that approved for the listed name-brand drug, making it possible to comply with both state and federal requirements. *See Cooper v. Wyeth, Inc.*, Civ. A. No. 09-929-JJB, 2012 WL 733846, at *4 (M.D. La. Mar. 6, 2012); *Del Valle v. Pliva, Inc.*, Civ. A. No. B:11-113, 2011 WL 7168620, at *7 (S.D. Tex. Dec. 21, 2011) ("It appears that PLIVA and Teva's 2004 failure to update the labeling—to match that of the brand name drug—could place the claims against these two generic manufacturers outside of the preemption described in *Mensing*."); *Fisher v. Pelstring*, Case No. 4:09-cv-00252-TLW, D.E. 202, at 6–7 (D.S.C. Sept. 30, 2011). Generic Defendants were preempted by federal law

from including additional warnings not approved by the FDA; however, they could, and indeed they were required to, ensure that their labeling contained the stronger, FDA-approved warnings for the name-brand drug.

Based on the allegations set forth in Plaintiffs' Fourth Amended Complaint regarding the failure of Generic Defendants TEVA, Watson Labs, and Watson Pharma to update their labels to conform with the name-brand manufacturers' FDA-approved labels, the Court concludes that Plaintiffs' claims against Generic Defendants TEVA, Watson Labs, and Watson Pharma are not preempted by federal law because it was possible for them to comply with both Texas and federal law. Plaintiffs' failure-to-update claims against Pliva, Inc., Barr Laboratories, Inc., and Barr Pharmaceutical, LLC, however, are preempted by federal law, as there are no allegations that their labels were inconsistent with the FDA-approved, name-brand drug labels.

B. TEX. CIV. PRAC. & REM. CODE § 82.007

Next, Generic Defendants argue that Plaintiffs' failure-to-update claims must be dismissed because they are barred by TEX. CIV. PRAC. & REM. CODE § 82.007, which establishes a rebuttable presumption that a drug manufacturer or distributor is not liable if the warnings and information that accompanied its product were approved by the FDA. (D.E. 57 at 10–15.) Plaintiffs argue that their claims are excepted from the Section 82.007 rebuttable presumption because Generic Defendants committed a fraud on the FDA by withholding required information from the agency and making material misrepresentations regarding the drug's performance. (D.E. 63 at 23–25.)

In *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372, 381 (5th Cir. 2012), the Fifth Circuit held that the Section 82.007(b)(1) fraud-on-the-FDA exception "is preempted by the FDCA unless the FDA itself finds fraud." As Plaintiffs failed to allege that the

FDA has made a finding of fraud, Plaintiffs' allegations are insufficient to establish a plausible fraud-on-the FDA exception. *See Phares v. Actavis*, Civ. No. B:11-63, 2012 WL 3779227, at *7 (S.D. Tex. Aug. 30, 2012); *Del Valle v. Qualitest Pharm. Inc.*, Civ. No. B-11-113, 2012 WL 2899406, at *3 (S.D. Tex. June 22, 2012). Yet, it is only necessary to plead facts establishing an exception to a Section 82.007 presumption of no liability if a complaint's factual allegations first give rise to such a presumption. *See Eckhardt v. Qualitest Pharmaceuticals Inc.*, 858 F. Supp. 2d 792, 799 (S.D. Tex. 2012) ("Plaintiffs' second amended complaint apparently assumes that the warning and information accompanying Eckhardt's metoclopramide were approved by the FDA. Thus, Generics appear to be statutorily protected from liability.").

Section 82.007 provides a rebuttable presumption of no liability for a defendant manufacturer only if "the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act . . . ." § 82.007(a)(1). In their briefing, neither side addresses the situation where a generic manufacturer consistently fails to include the most recent FDA-approved warning labels with its product. However, based on the plain language of the statute, the Court concludes that, before a drug manufacturer may assert a presumption of no liability under Section 82.007, the drug manufacturer must first demonstrate that it distributed its product with the proper FDA-approved warnings and information.

The Fourth Amended Complaint alleges that Generic Defendants TEVA, Watson Labs, and Watson Pharma "failed to adhere to the FDA label requirements." (D.E. 72 at 18.) Accepting these allegations as true, the Court concludes that Generic Defendants TEVA, Watson Labs, and Watson Pharma are not entitled to a Section 82.007 presumption of no liability, at least not at this stage of the proceedings.

CONCLUSION

For the reasons set forth above, Generic Defendants' motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(c) (D.E. 57, 65) is GRANTED IN PART AND DENIED IN PART.

Plaintiffs' failure-to-warn claims against Defendants TEVA Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. are retained.

Plaintiffs' failure-to-warn claims against Defendants Pliva, Inc., Barr Laboratories, Inc., and Barr Pharmaceutical, LLC are DISMISSED for failure to state a claim upon which relief can be granted.

ORDERED this 7th day of March, 2013.

NELVA GONZALES RAMOS
UNITED STATES DISTRICT JUDGE